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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,723	12/10/2004	Peter Neu	00143-00245-US	6056
23416	7590	07/24/2006	EXAMINER	
CONNOLLY BOVE LODGE & HUTZ, LLP			ARNOLD, ERNST V	
P O BOX 2207			ART UNIT	PAPER NUMBER
WILMINGTON, DE 19899			1616	

DATE MAILED: 07/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/517,723

Applicant(s)

NEU ET AL.

Examiner

Ernst V. Arnold

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2-7 and 9-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2-7 and 9-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 4/10/2006.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

### **DETAILED ACTION**

The Examiner acknowledges receipt of remarks filed on 5/18/2006. Applicant's arguments have been fully considered. Applicant's amendments have necessitated new grounds of rejection. Applicant has cancelled claims 1, 8, 15 and 16. Accordingly, claims 2-7 and 9-14 are pending in the application.

#### **Withdrawn rejections:**

1. Claims 6 and 7 were rejected under 35 U.S.C. § 101 as being drawn to use claims, which are non-statutory process claims, as defined in 35 U.S.C. § 101. Applicant has amended the claims to be method claims and the Examiner withdraws the rejection.

2. Claims 6 and 7 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has amended the claims to overcome this rejection and it is withdrawn.

3. Claims 1-3 were rejected under 35 U.S.C. 102(b) as being anticipated by Fishman (US 5,228,434). Applicant has amended the claims to depend from the method claim 6. Fishman does not teach the instant methods and the rejection is withdrawn.

4. Claims 1 and 4-7 were rejected under 35 U.S.C. 102(b) as being anticipated by Briend et al. (WO 97/15311) and Briend et al. (US 5,670,177). Briend et al. do not teach the instant method and the Examiner withdraws the rejection.

5. Claims 1-44 have been cancelled in copending application 10/380,869 in an amendment filed on 6/6/2006 thus making the provisional double patenting rejection over instant claims 1 and 3 moot.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 is dependent on a cancelled base claim (claim 8) and it is unclear to the Examiner the metes and bounds of these claims. For purposes of Examination, the Examiner will examine the claims as if they were dependent from the only independent claim 6.

Claims 2-6 and 9-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant amended claim 6 to recite: "...wherein what is administered...". It is unclear to the Examiner what "what" is. The Examiner suggests replacing "what" with "gas mixture" which finds support in the line immediately above. The claim will be interpreted in this way for purposes of examination. Claims 2-5 and 9-14 are rejected as being indefinite because they are dependent on an indefinite base claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2, 3, 6, 7, 10, 11, 13, and 14 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Petzelt et al. (WO 00/53192).

Petzelt et al. disclose preparations and methods of use of xenon or xenon gas mixtures for treating neurointoxications (a chronic cerebral disorder such as Parkinson's disease) in a therapeutically useful concentration (Page 5, paragraph 1; page 11, paragraph 4 and claims 1, 7 and 16, for example). The preparation can have a ratio of xenon to oxygen of 80 to 20 percent by volume thus reading on instant claims 2, 6, 10, 11 and 13 (Page 8, second paragraph and claims 15 and 17). Administration is by simple inhalation (Page 12, line 1). Methods of mixing the gases are provided (Page 8, paragraphs 3 and 4). Methods of administration are also provided (Page 9, paragraphs 1 and 2). Petzelt et al. also disclose a gaseous mixture of xenon and air (Page 8, last paragraph). Air is known in the art to contain oxygen and inert gases thus anticipating instant claim 3 and 14.

**Response to arguments:**

Applicant asserted that the prior art disclosure of Petzelt et al. teaches treatment of an existing disorder and does not include as a step the selecting as a patient some one having the specified condition and then administering the xenon to that patient to treat the condition. The Examiner respectfully disagrees. First, in order to select a patient with a disorder, one must identify the disorder in the patient, which Petzelt et al. discloses. Petzelt et al. teaches, for example, treating someone with Parkinson's disease or craniocerebral trauma or ischemia (thus identifying the patient population) and then administering a gaseous mixture most preferably 75-70:25-30 % by volume xenon:oxygen mixture to that patient thus reading on instant claim 6 (Page 7, last paragraph - page 8, first two paragraphs). The Examiner interprets a patient with

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Parkinson's disease to have impairment of cognitive performance thus reading on instant claim

7.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

1) Claims 2-7 remain/are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4, 7, and 9-11 of copending Application No. 10/518,067. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims. The Examiner interprets NO to be a homogenous medicament because it is transported by the blood stream and thus instant claim 4 makes obvious instant copending claim 2. Instant claim 2 renders obvious gaseous xenon present in a therapeutically effective amount of copending claims 3, and 10. The gaseous preparation of instant claim 4 makes

obvious inhalation of copending claims 4 and 11. Instant claim 7 is drawn to the use of a xenon gas mixture for cerebral protection, which makes obvious copending claim 9.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

2) Claims 2 and 4-7 remain/are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-4, 7 and 9 of copending Application No. 10/517,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims embrace or are embraced by the copending claims. Instant claim 2 and copending claim 2 are drawn to therapeutically effective amounts of xenon. Instant claim 4 comprises an NO source and xenon which makes obvious copending claims 4 and 7 composition comprising xenon and a spasmolytic. NO is a spasmolytic. Instant claim 5 and copending claims 2 and 3 are drawn to therapeutically effective amounts of NO and xenon. Instant claim 6 and copending claim 7 are drawn to the use of the xenon containing gas mixture. Instant claim 7 and copending claim 9 are drawn to the use of xenon for the therapy or prophylaxis of impairments of cognitive performance.

One of ordinary skill in the art would have recognized the obvious variation of the instant claims in the copending application because of the overlap in claimed subject matter as stated above.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

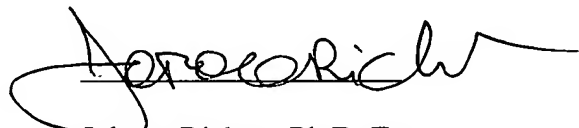
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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